Message

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Sent: 5/18/2021 3:45:27 PM
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CC: Hughes, Hayley [hughes.hayley@epa.gov]
Subject: FW: OCSPP News for May 17, 2021 -- MC
Attachments: Inside TSCA Newsletter 5.17.21.pdf

- Inside TSCA 05/14; EPA Plans To Drop Use-Specific Findings In Methylene Chloride Evaluation

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Sent: Monday, May 17, 2021 5:16 PM
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Subject: OCSPP News for May 17, 2021

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'It's a mess': Groups pan Regulations.gov overhaul

Kelsey Brugger, E&E News

https://www.eenews.net/greenwire/2021/05/17/stories/1063732761?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

Advocacy groups are unhappy with the federal regulation website's face-lift that was begun in the Trump administration and finalized under President Biden.

Seven progressive groups and the Natural Resources Defense Council argue in a letter today that the redesign of the General Services Administration's Regulations.gov website created "substantial and unacceptable barriers to the work of organizations."

"The new version of the website, conceived and planned during the Trump administration, represents an extraordinary retrenchment in public access," groups led by Democracy Forward wrote. "GSA has an opportunity and obligation to correct this issue."

The groups asserted that the website overhaul was woefully underfunded and neglected to follow its own protocols for public input.

The letter lists a number of problems: E-dockets are difficult to find, comments are hard to read and submit, comments are difficult to sort, and users can't download comments in bulk or sign up for email notifications.

"The biggest issue is the accessibility of the comment dockets — for journalists and also for advocates," said Matt Kent, a regulatory advocate at Public Citizen. "It wasn't great on the old site, but now it's a mess."

The other groups signing on included Georgetown Law's Institute for Constitutional Advocacy and Protection, the National Health Law Program, the National Center for Youth Law, Planned Parenthood and the Center for Science in the Public Interest.

Kent said he doesn't believe the issue is political, but he expressed frustration with how the new website was rolled out.

GSA held public input sessions in 2019, but he argued that the effort was lacking and focused too much on fraudulent comments, "which is certainly a concern but not the main concern."

"There was certainly a lack of attention to detail," he added.

GSA began making changes to the site in 2019 and launched a beta testing period.

The agency did not respond to a request for comment this morning. But the website homepage addresses the new look: "The new Regulations.gov is a re-envisioning of classic Regulations.gov, with enhanced search capabilities, a simplified commenting process, and an interface that adapts to various screen sizes for mobile devices."

GSA will continue to collect feedback and update its website, the homepage says. It notes that the site will eventually bring back the email notifications feature.

EPA drops mask mandate for vaccinated people
Kevin Bogardus, E&E News
https://www.eenews.net/greenwire/2021/05/17/stories/1063732763

EPA is no longer requiring masks for fully vaccinated people in its facilities, stoking fears among staff about potential exposure to the COVID-19 virus.

The move comes after the Centers for Disease Control and Prevention announced last week that it had updated its guidelines related to the pandemic, specifying that people vaccinated against the virus would not have to wear masks in outdoor or indoor settings under most circumstances. EPA has followed suit.

"Fully vaccinated employees, fully vaccinated onsite contractors, and fully vaccinated visitors to EPA facilities are no longer required to wear masks or physically distance in any workplace setting," said an internal email obtained by E&E News.

The email, sent Friday to EPA employees, added that the federal government was following CDC guidance and not local requirements. It also clarified what the announcement meant for individuals.

"If you are fully vaccinated (at least 2 weeks past your final dose), you are no longer required to wear a mask," said the email. "If you are not fully vaccinated (at least 2 weeks past your final dose), please continue to wear a mask consistent with the requirements set forth in the EPA Workplace Safety Plan."

No proof of vaccination is required, and signs around EPA offices will be updated, the email said. In addition, there are no other changes to EPA's policies at this time.

"Maximum telework and workplace occupancy limits remain in place," the email said.

The change in EPA's stance on masking worried agency staffers.

"I was surprised by the CDC announcement and shocked at how quickly EPA is to remove the requirement," one EPA employee who has been fully vaccinated told E&E News. "Regardless of what the CDC says, I and my family are still wearing masks."

Another EPA staffer said they were surprised that keeping mask requirements for everyone didn't apply to federal office space, adding they were worried that some vaccinated people "may be asymptomatic carriers and infect unvaccinated people who won't wear masks for their own protection."

An EPA spokesperson referred questions from E&E News for this story to the Office of Management and Budget.

"With the release of new CDC guidance on mask wearing, fully vaccinated agency staff, contractors and visitors no longer have to mask in federal buildings or on federal lands," an OMB official told E&E News.

OMB sent an email last week to federal agencies outlining the updated guidelines on masking for vaccinated people and said it was consistent with President Biden's executive order on protecting the federal workforce.

Since March 2020, when the pandemic took hold in the United States, the vast majority of EPA employees have been teleworking to avoid exposure to COVID-19.

The Trump administration put forth a phased reopening plan for the agency that stirred up anxiety among staff. Yet EPA has never fully reopened, and that phased approach has been tossed by the Biden administration (Greenwire, April 23).

Instead, agency offices have 25% occupancy limits, and "a posture of maximum telework" is maintained under EPA's workplace safety plan.

EPA employees said they hope the agency will hold off on reopening fully to gauge the impact of the new CDC guidance.

One EPA employee told E&E News he believes agency staff will understand the science behind the CDC move on masking "and be more than happy to take another big step towards normalcy again."

"As far as coming back to the building, I think this moved us closer but would still doubt we go rushing back before we know what's going on with children vaccines and the school year next year," the EPA employee said.

Reopening during the pandemic has been fraught at EPA.

Union officials and agency employees have resisted such plans to bring staff back to the office. In addition, in August last year, EPA signed an agreement on reopening with its largest union, the American Federation of Government Employees, that noted that while CDC...

US EPA signals shift to making substance-wide TSCA risk determination

Terry Hyland, Chemical Watch

https://chemicalwatch.com/265476/us-epa-signals-shift-to-making-substance-wide-tsca-risk-determination

The US EPA has told a federal appeals court that it plans to "revisit" the previous administration's decision to make TSCA risk determinations for methylene chloride based on individual conditions of use (CoUs), and will instead evaluate whether the substance as a whole presents an unreasonable risk.

The agency said it also wants to review previous assumptions on workers' use of personal protective equipment (PPE) and exposures to communities near emitting facilities.

The court filing is the clearest indication yet of how the EPA plans to revisit TSCA risk evaluations completed under the previous administration to address worker protections and environmental justice concerns.

The EPA laid out its plans for methylene chloride in a brief filed with the US Court of Appeals for the Ninth Circuit on 13 May. The agency asked the court to remand the EPA's June 2020 risk evaluation of methylene chloride so it can reconsider the assessment.

In its 2020 TSCA risk evaluation, the EPA said the solvent poses an unreasonable risk to workers, occupational non-users,

consumers and bystanders in 47 out of 53 evaluated CoUs. Several groups ultimately challenged the agency's findings, arguing in part that the EPA's "use by use" approach to risk evaluation violates TSCA.

Michal Freedhoff, who serves as the acting head of the agency's chemicals offices, told the court that the agency now intends to "make a binary determination of whether the chemical substance, methylene chloride, presents unreasonable risk of injury to human health or the environment".

The filing also signals potential changes ahead for the other nine substances that have completed risk evaluations.

"Some of the approaches taken in the methylene chloride risk evaluation arise not only in this risk evaluation, but in other [TSCA] risk evaluations as well," the EPA told the Ninth Circuit. Earlier this month, the EPA asked the same federal appeals court to send back the final risk evaluation for HBCD so it could reconsider that assessment.

Risk management continues

If granted, the EPA told Chemical Watch, remanding the action would leave the "no unreasonable risk" determinations for methylene chloride in place while the agency reconsiders the evaluation. It would also allow the agency to continue to develop a risk management rule to mitigate already-identified unreasonable risks from methylene chloride, the agency said.

TSCA gives the EPA until the end of June to propose a risk management rule for methylene chloride.

"EPA will work to complete the risk management rulemaking as soon as possible, taking into account the reconsideration EPA intends to conduct," the agency said.

If granted, the agency said it expects the reconsideration of the methylene chloride risk evaluation and any resulting agency actions "to be finalised within 12–18 months".

PPE, fenceline communities

A review of the risk evaluation would also give the EPA a chance to address assumptions made by the previous administration that have drawn criticism from several groups.

Labour groups, NGOs, several US states and even the EPA's Science Advisory Committee on Chemicals (Sacc) have questioned the agency's assumptions on workers' use of PPE. A study published last month indicated that fatalities from methylene chloride exposure – mostly involving workers – could be higher than previously reported.

Assuming use of PPE "could lead to an underestimation of the risk to workers", the EPA said in its court filing. Remand will allow the agency to reconsider these assumptions, it said.

In addition, the EPA said that during the risk management phase it would evaluate whether it should "more properly consider the use of PPE" as well as other occupational safety practices.

The EPA also previously excluded evaluations of exposure from pathways that fall under the jurisdiction of other statutes, like the Clean Air Act. As a result, the agency's evaluation of methylene chloride did not assess emissions from...

EPA extends notification deadline for updates to confidential status of TSCA chemicals

Julia John, Chemical Watch

https://chemicalwatch.com/265477/epa-extends-notification-deadline-for-updates-to-confidential-status-of-tsca-chemicals

The US EPA has extended the deadline for commenting on its plan to drop confidentiality protections for hundreds of substances on the TSCA inventory. Stakeholders now have until 30 June to reach out with comments, questions or concerns about the change.

Last month the EPA listed 390 substances expected to lose their confidential chemical identity status and go to the public part of the inventory, setting a deadline of 14 May for parties to notify the agency of any mistakes. On 14 May, the agency said in an update that it extended the deadline "in response to industry stakeholder requests for additional time to review this list".

According to the EPA, two requesters – the American Chemistry Council (ACC) and BASF – said that some listed substances could overlap with those reported during the inventory reset process under the Active-Inactive rule, and that the EPA developed the list using just the 2020 Chemical Data Reporting (CDR) rule submissions.

The EPA said it intends to declassify the substances from those submissions because they were reported as non-confidential by at least one manufacturer between 2012 and 2020, "effectively saying it is not a secret that the chemical is in US commerce".

"The agency did an extensive review of each individual instance in which confidential status was not requested for these chemical identities in order to confirm the accuracy of the list," the agency said.

It also recognised concerns about overlap with the Active-Inactive rule, which mandated identification of substances produced, imported or processed in the country during the 10-year time period ending on 21 June 2016.

However, the EPA said for each of the substances it is now looking at, "there is also one or more independent CDR-based (and EPA-validated) reasons to consider the chemical identities to be no longer eligible for inclusion on the confidential portion of the inventory".

It plans to update the TSCA inventory listings with specific chemical identities this summer.

Medline and Sterigenics haven't reported cancer-causing ethylene oxide emissions to the EPA's pollution inventory for years
Michael Hawthorne, Chicago Tribune
https://www.chicagotribune.com/news/environment/ct-ethylene-oxide-cancer-epa-medline-sterigenics-tt-20210517-ovk3a2fckbeftfkubortxhal54-story.html

Nearly every major industrial source of ethylene oxide makes it relatively easy for Americans to know how much of the cancer-causing gas drifts into surrounding communities.

The only outliers are two Illinois-based companies that for years have failed to report emissions to the Toxics Release Inventory, a Tribune review of federal records found.

A Medline Industries plant in north suburban Waukegan last appeared in the inventory during the mid-2000s, even though the U.S. Environmental Protection Agency later determined the facility has been responsible for some of the nation's highest cancer risks from air pollution.

Oak Brook-based Sterigenics stopped filing annual reports with the EPA in 2018, the same year neighbors and political leaders fought to shut down one of the company's sterilization plants in west suburban Willowbrook.
Sterigenics closed the Willowbrook plant in 2019. It still uses ethylene oxide to fumigate medical equipment in eight other cities, including suburbs of Atlanta and Los Angeles. But the past four years of emissions are absent from the EPA's inventory — omissions the agency refused to address during the Trump administration.

Annual pollution disclosures are the least that should be required from corporations, environmental activists said, especially when it comes to chemicals that thousands of Americans breathe every day.

"Transparency is key," said Celeste Flores, a Gurnee resident who grew up in the area and now lives a mile from Medline's assembly plant at Skokie Highway and Pulaski Drive in Waukegan.

"They might be a top employer in our community, but their commitment needs to include our health in addition to jobs," said Flores, co-chair of Clean Power Lake County, a local environmental group.

The need for more information from chemical manufacturers and users became a global priority in 1984 when a Union Carbide plant released a burst of methyl isocyanate, an extremely toxic gas that killed at least 3,800 and, by some accounts, as many as 16,000 people in Bhopal, India.

After the same chemical leaked from another Union Carbide plant in West Virginia, Congress responded with the Emergency Planning and Community Right-to-Know Act, a law that required scores of companies to begin filing annual reports about pollution released into air, water and soil.

By making the information readily available to the public, the EPA says on its website, the pollution inventory "creates a strong incentive for companies to improve environmental performance." The agency posts the data online, and with a few clicks anyone can discover information about specific industries, facilities and about 650 different chemicals.

Medline and Sterigenics began facing scrutiny after the EPA updated its national map of cancer risks from certain airborne chemicals.

The new map, released in August 2018, reflected a scientific consensus that ethylene oxide is far more dangerous than previously thought. As a result, the EPA determined, more than half a million Americans face unacceptable cancer risks, mostly from breathing the toxic gas, also known as EtO.

Exposure to even small concentrations dramatically increases the chances of being diagnosed with breast cancer, leukemia and lymphomas during a person's life, the EPA and two panels of independent scientists concluded.
Though its competitors disclose EtO releases through the EPA's pollution inventory, Sterigenics said it isn't required to do so. "The company reports emissions to relevant state authorities in accordance with the requirements under its permits," the company said in a two-sentence response to questions.

Medline also said it reports emissions to state authorities. In Illinois at least, public access to the obscure filings requires a Freedom of Information Act request.

President Joe Biden's administration is pledging to make it clear all EtO users should file annual Toxics Release Inventory reports.

'Blind spot' in Biden's infrastructure plan: Lead paint
Ariel Wittenberg, E&E News
https://www.eenews.net/greenwire/2021/05/17/stories/1063732753?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

President Biden's proposal to get the lead out of the nation's pipes has some experts wondering: What about the paint?

Banned decades ago for its neurotoxic effects, lead can inhibit brain development in children and cause behavioral issues. Overall, lead exposure to kids has been estimated to cost society $50 billion in lost wages annually. But lead persists in pipes and paint across the country, particularly in older and low-income housing stock whose residents can't afford to update their homes.

Lead contamination in drinking water has received national attention since tap water in Flint, Mich., tested for extremely high levels of the neurotoxin. As a result, President Biden and House lawmakers have pledged to spend $45 billion on removing every remaining lead pipe in the nation.

Much less attention — both in the news and in legislation — has been paid to lead paint, even though it is the biggest source of exposure for children between 1 and 6 years old. Those young kids will often accidentally ingest paint chips or dust while crawling or sucking on their hands and toys.

Lead paint is also more common than lead pipes. EPA estimates there are between 6 million and 10 million lead pipes nationwide, while about 24 million housing units have significant lead-based paint hazards, according to the Centers for Disease Control and Prevention.

But Biden's American Jobs Plan doesn't propose any specific pot of money dedicated to lead paint removal. Rather, such remediation efforts would be rolled into the proposed $40 billion to improve infrastructure of public housing, which, in addition to mitigating "imminent hazards to residents" like lead, would also go toward energy efficiency measures and other improvements.

"This is the predominant source of poison, and yet it feels like it was somehow missed," said Ruth Ann Norton, president and CEO of the Green & Healthy Homes Initiative. "It is a big blind spot."

Norton says the plan needs to "articulate dedicated investments" in lead paint remediation. Her group sent a letter to Housing and Urban Development Secretary Marcia Fudge last month asking for a $45 billion carve-out — an amount that could create more than 3.7 million lead-safe homes.

"You could not have a clearer example of an opportunity to change the trajectory of racial equity than by improving the health of housing, because when you do, kids who are not brain damaged by lead will get into classes healthy, ready to learn and ready to compete for a lifetime," Norton said. "But you have to do lead-based paint. There's just no way around it."

Her request mirrors a set-aside in the "Environmental Justice Legacy Pollution Cleanup Act of 2021" that Sen. Cory Booker (D-N.J.) and Rep. Donald McEachin (D-Va.) plan to introduce in the coming weeks. An aide in Booker's office said that the senator came to understand paint's contribution to childhood lead exposure as mayor of Newark, N.J., and that including $45 billion for low-income housing lead paint removal in a "once-in-a-lifetime" infrastructure investment package "is a top priority for him."

Separately, the National Center for Healthy Housing wrote congressional leaders earlier this month asking for an infrastructure package to include a $19 billion carve-out to pay for replacing 25 million lead-contaminated windows. Though the effort would not eliminate lead paint in housing, windows are a major source of lead exposure to kids because paint breaks up into dust as they are opened and closed. Replacing lead-contaminated windows, which, by definition, are common in older housing stock, would also have secondary gains in energy efficiency and climate mitigation.

"Addressing lead paint and healthy homes as part of a strategy to provide upgraded, resilient, more equitable and affordable housing in the infrastructure plan promises a transformational change," the center writes. "Our nation's homes truly cannot be resilient or affordable without also being healthy and safe."...

Ewire: Groups pressure EPA to ramp up EtO air data collection

N/A, Inside EPA

https://insideepa.com/daily-feed/ewire-groups-pressure-epa-ramp-eto-air-data-collection

Communities in the Chicago area living near industrial facilities that use the carcinogenic solvent ethylene oxide (EtO) are pressing EPA to swiftly follow through with plans to expand requirements for companies to report their emissions of EtO and for the agency to provide greater oversight of the facilities.

The Chicago Tribune reports May 17 that local community activists want medical sterilization facilities in the area to fully report their EtO emissions, following a years-long gap during the Trump administration when some reporting stopped.

"More testing and better oversight of these facilities is sorely needed in Illinois," according to the group Stop EtO in Lake County, the Tribune says.

EPA is planning to expand reporting requirements for its Toxics Release Inventory (TRI) to include more EtO-emitting facilities, after sterilization company Sterigenics -- one of the highest-profile emitters -- stopped reporting its EtO emissions data to the TRI in 2017. The company did so apparently based on its own determination that it could take advantage of one of the exemptions from reporting, such as if it fell below the minimum threshold of 10,000 pounds of releases per year.

The Tribune reports that "Nearly every major industrial source of ethylene oxide makes it relatively easy for Americans to know how much of the cancer-causing gas drifts into surrounding communities," but the "only outliers are two Illinois-based companies that for years have failed to report emissions to the Toxics Release Inventory, a Tribune review of federal records found."

The companies are Sterigenics, based in Oak Brook, IL, and a Medline Industries plant in Waukegan. Sterigenics already closed a facility in Willowbrook, IL, in 2019, following pressure from the community and political leaders over its EtO emissions.

In an April 29 statement announcing the planned expansion of TRI, EPA Administrator Michael Regan said, "Every person in the United States has a right to know about what chemicals are released into their communities. By requiring new and more data on chemical releases from facilities, EPA and its partners will be better equipped to protect the health of every individual, including people of color and low-income communities that are often located near these facilities but have been left out of the conversation for too long."

But EPA did not specify in detail what criteria it will now use for EtO-emitting facilities, saying only that it intends to crack down on "certain contract sterilization facilities" that use EtO and "will provide more details in upcoming months on its effort to require these contract sterilization facilities to report to TRI and will keep the public informed as next steps are determined."

Meanwhile, EPA announced May 10 that it will take comment for 30 days on a new Information Collection Request (ICR) to support its technology review of the 1994 national emissions standards for hazardous air pollutants (NESHAP) for the commercial sterilization and fumigation sector, including EtO emissions.

The sector is one of several where EPA's Office of Inspector General (OIG) is urging EPA to adopt tougher air toxics rules, although the agency so far has pushed back against the OIG's recommendations, arguing they are too narrow and prescriptive, indicating only that it will consider possible health risk reviews when it conducts scheduled control technology reviews in the coming years.

Split Appellate Panel Orders EPA To Overhaul Suite Of Lead Standards

Suzanne Yohannan, Inside EPA

https://insideepa.com/daily-news/split-appellate-panel-orders-epa-overhaul-suite-lead-standards

A divided federal appellate panel is ordering EPA to overhaul a suite of hazard standards that the Trump administration set in 2019 for lead paint and its dust, in a ruling that is a win for environmentalists while handing Biden officials an

opportunity to strengthen the policies.

In a May 14 ruling in A Community Voice, et al. v. EPA, a three-judge panel of the U.S. Court of Appeals for the 9th Circuit found in a 2-1 decision that the lead-dust hazard standards EPA set for determining safety levels in residential properties are unlawfully weak, while also calling on officials to reconsider corresponding lead dust clearance levels, which are used to determine whether such properties are safe after construction.

The court is also requiring EPA to update both its lead-based paint (LBP) definition, which is used to determine lead levels in paint, and its soil-lead hazard standards.

The panel remanded without vacatur the regulatory package, known as the lead dust hazard standards (DLHS), which EPA had issued in 2019 as required by a 2017 ruling from the 9th Circuit.

In its new ruling, the panel holds that EPA's lead dust standards and in some cases its lack of regulatory action violated the Residential Lead-Based Paint Hazardous Reduction Act (PHA), which is codified in Title IV of the Toxic Substances Control Act (TSCA), contradicted congressional intent and Supreme Court interpretations and in some cases was arbitrary and capricious.

The court charged the agency's definitions of lead-based paint hazard standards violated TSCA's requirement that "EPA identify 'any condition' of lead in dust, paint, and soil that would result in 'adverse human health effects as established by the administrator under [TSCA Title IV].'"

The ruling comes after the Biden administration had won a stay in the case until April 30 in order to give it more time to review the agency's position on the matter, even after the case was argued before the court last fall.

It is unclear whether EPA will seek to further appeal the ruling. Tightening its lead rules could fit with its plans to aggressively address lead contamination and prioritize protections for environmental justice communities.

But regardless of how the administration proceeds, environmentalists are hailing the majority ruling, "We're grateful that the 9th Circuit determined the EPA's weak standards violate the law and failed to protect children," attorney Johnathan Smith says in a May 14 release from Earthjustice, which represented the petitioners.

"There is no safe level of lead exposures for children. Strengthening the standards will protect millions of children from exposure to dangerous levels of lead dust at their homes and schools," he added.

At issue was whether EPA could consider factors such as feasibility and cost when it sets such standards, as the agency argued, or if it was limited to basing it solely on its health risk assessment, which environmentalists contended. But the majority opinion, written by Judge Mary Schroeder and joined by District Judge Lawrence Piersol, sitting by designation, rejected EPA's arguments, saying the statute bars the agency from considering costs when setting such standards.

She writes that the agency "reasons that because it is now well established that any level of lead in the blood leads to adverse health effects, the statutory language gives the EPA discretion to select hazard standards it wishes to enforce, rather than ones aimed at eliminating health risks."

"Congress, however, said that the EPA was to look at risks to health. We interpret the statute accordingly," she said. "The current dust-lead hazard standards, lead-based paint definition, and soil-lead hazard standards do not identify all levels of lead that lead to adverse human health effects and therefore violate the TSCA," she finds.

Not Health Protective

On the DLHS, the court notes TSCA differentiates between identification of lead-based paint hazards and implementation...

Fate Of Wheeler's 2035 Deadline To Eliminate Animal Testing Remains In Flux

Maria Hegstad, Inside TSCA

https://insideepa.com/tsca-news/fate-wheeler-s-2035-deadline-eliminate-animal-testing-remains-flux

EPA's computational toxicology research chief says there has been no decision on whether to preserve former Administrator Andrew Wheeler's directive to largely eliminate the agency's use of animal testing by 2035, after he and a former official described it as too aggressive -- though potentially useful to help "focus" work on the subject.

"No decision has been made" on the future of Wheeler's 2019 directive, Rusty Thomas, director of the computational toxicology center in EPA's research office, said in response to a reporter's question during a May 13 webinar on use of new alternate methods (NAMs) for evaluating chemicals. "That's the short answer."

But he and other speakers on the webcast, which was hosted by the Environmental Law Institute, Johns Hopkins University, Physicians Committee for Responsible Medicine and UCLA law school's Emmett Institute on Climate Change and the Environment, said they doubt NAMs will be able to fully replace animal-based toxicity tests by 2035 as Wheeler sought.

For instance, Penny Fenner-Crisp, who is retired from EPA after a lengthy career as a toxicologist and risk assessor in its toxics and pesticide offices, said she felt the 2035 deadline is too soon. "The science just won't move fast enough, no matter how much money you put into it."

And while Thomas stopped short of predicting use of NAMs will fall short of Wheeler's target, he said the 2019 directive may have been too "ambitious."

"That goal outlined out by the previous administrator in that 2019 memo was certainly ambitious . . . In my own opinion, it was overly ambitious," he said.

Wheeler's 2019 directive sought to reduce EPA requests for, and funding of, mammal studies by 30 percent as of 2025 and to eliminate all mammal study requests and funding by 2035, though the administrator would be able to approve animal testing orders outside those limits as needed.

The directive also required the agency to "come as close as possible to excluding from its approval processes any reliance on mammal studies conducted after January 1, 2035, including those performed by third parties, subject to applicable legal requirements."

But a Biden appointee has doubted whether they will stick to that timeline, including EPA Office of Research and Development (ORD) deputy chief Chris Frey. He and career acting ORD chief Jennifer Orme-Zavaleta said on Feb. 2 that they planned to review the directive with EPA Administrator Michael Regan, who was then awaiting his confirmation hearing.

"I have no doubt we'll continue developing NAMs, but the question is whether they agree with those goals for reducing animal testing and the path that we laid out to do that," Orme-Zavaleta said at the time.

NAMs generally encompass toxicity testing other than on living animals, such as through computational modeling or on cell cultures. Supporters of the methods say they offer a way to better analyze chemicals' likely effects on humans and reduce harm to lab animals, but critics charge that NAMs in their current forms cannot show a chemicals' effect on a complete organism.

'Help Focus Efforts'

During the May 13 webcast, Thomas said that while Wheeler's goals may be difficult to achieve they still could function

as aspirational targets.

He argued that "in many cases, goals for action help focus efforts toward the problem and I think that was part of the intent. The Agency is not going to sacrifice protection of public health and the environment necessarily to meet that goal, but it helps prioritize efforts to try to develop and apply these new approaches."

Fenner-Crisp agreed that even if EPA Administrator Michael Regan agrees the 2035 deadline is unachievable, he will probably retain it in some form, saying she "can't imagine the agency abandoning it..."

Another speaker at the meeting, Paul Locke, associate professor of public health at Johns Hopkins University agreed, pointing to EPA's work to advance NAMs use since Congress reformed the Toxic Substances...

EPA Plans To Drop Use-Specific Findings In Methylene Chloride Evaluation
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/epa-plans-drop-use-specific-findings-methylene-chloride-evaluation

EPA says in a new court filing that it intends to drop the Trump-era practice of making separate risk findings for each condition of use it reviewed in the TSCA evaluation of methylene chloride, and to instead craft a single "binary" determination for the chemical, with EPA seeking a remand of the evaluation to rework it under that model.

"EPA intends to propose transitioning to instead make a binary determination of whether the chemical substance, methylene chloride, presents unreasonable risk of injury to human health or the environment," President Joe Biden's nominee to lead EPA's toxics office, Michal Freedhoff, writes in a May 13 declaration to the U.S. Court of Appeals for the 9th Circuit, which is hearing suits over the evaluation in the joined cases Neighbors for Environmental Justice, et al., v. EPA et al. and State of New York et al. v. Andrew Wheeler.

That approach promises to fundamentally change not only how EPA implements the Toxic Substances Control Act's (TSCA) mandate to determine whether existing chemicals pose "unreasonable risk," but how it crafts risk-management rules based on those determinations and how stakeholders can challenge the evaluations in court.

Freedhoff's declaration is paired with a motion seeking voluntary remand without vacatur of the final methylene chloride evaluation -- meaning its use-by-use risk determinations would remain in effect until EPA finalizes any revisions. The evaluation found that 47 of the 53 commercial, industrial and consumer uses the agency studied pose unreasonable risks.

Under the Trump-era model, EPA can regulate only those uses that it finds to carry unreasonable risks, while a single "binary" finding would give the agency much more discretion in its rulemaking process. Meanwhile, industry could gain new opportunities to challenge the evaluations, because under the use-by-use model EPA only considered the parts of an evaluation that identify uses that pose no unreasonable risks to be "final action" subject to suit.

By contrast, EPA said it would not consider the determinations that particular uses pose risks warranting regulation to be "final" until it enacted risk management rules based on those findings -- a process that under TSCA can take up to two additional years, and which it has yet to complete for any existing chemical.

Because of that "stovepiped" approach, the only suits filed so far over the 10 existing chemical evaluations completed by the Trump EPA come from environmental, labor and other groups who say the evaluations are not strict enough, while industry stakeholders have so far had no venue for claims that the risk findings are too stringent.

Freedhoff writes that she expects EPA's reconsideration of the evaluation "to be complete and any resulting agency actions related to the Risk Evaluation to be finalized within 12-18 months" -- setting an aggressive timeline for the agency to conduct any new analyses it needs, craft formal proposals and take public comment ahead of its final action.

That in turn would allow the agency to continue work on TSCA risk management rules for those uses, Freedhoff writes.

"EPA believes it would be most efficient to leave all determinations in place while EPA undertakes reconsideration," the declaration says. "Remand without vacatur will permit EPA to continue to work on the associated risk management rulemaking as appropriate to mitigate unreasonable risks of injury to health or the environment that the Agency found in the Methylene Chloride Risk Evaluation, while undertaking its reconsideration of the determinations of no unreasonable risk."

Freedhoff also notes that since EPA finalized its methylene chloride evaluation in June 2020 -- the first of 10 analyses it would complete before the end of the Trump administration -- the agency has already begun writing rules to address those risks and faces a statutory deadline to issue a proposal by June of this year. The statute gives EPA a one-year timeline to...

Court upholds $25M award in Monsanto cancer case

AP Staff, E&E News

https://www.eenews.net/greenwire/2021/05/17/stories/1063732735?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

A federal appeals court on Friday upheld a $25 million award against agribusiness giant Monsanto Co. in a lawsuit that alleged a California man developed cancer from exposure to its best-selling weedkiller, Roundup.

In a 2-1 ruling, a panel of the 9th U.S. Circuit Court of Appeals rejected Monsanto's appeal of punitive damages awarded in 2019 by a San Francisco jury.

The jurors found that Edwin Hardeman proved that Roundup's design was defective, it lacked sufficient cancer warnings, and its manufacturer was negligent. They initially awarded Hardeman more than $80 million in damages, but a judge later reduced the punitive portion of the award, bringing the total to around $25 million.

Hardeman blamed his non-Hodgkin lymphoma on decades of using Roundup products to treat poison oak, overgrowth and weeds on his San Francisco Bay Area property.

The appellate court ruling said evidence from the case supported a conclusion that Monsanto acted with "indifference to or a reckless disregard of the health or safety of others" and thus was liable for punitive damages.

And while the initial punitive award figure was excessive, the reduced amount was legal, the ruling said.

An email to Monsanto representatives seeking comment wasn't immediately returned.

However, Monsanto has long said studies have established that glyphosate, the active ingredient in its widely used weedkiller, is safe.

Hardeman's suit was one of many by thousands of people who contend that Monsanto's products caused their cancers.

Monsanto was acquired by the German chemical giant Bayer several years ago. Bayer agreed last year to pay $12 billion to resolve thousands of U.S. lawsuits and deal with future claims.

Reckoning for Roundup rolls on: Ninth Circuit Court upholds verdict in case against Monsanto

Julia Conley, Red, Green, and Blue

http://redgreenandblue.org/2021/05/15/reckoning-roundup-rolls-ninth-circuit-court-upholds-verdict-case-monsanto/

The 9th Circuit rejected an appeal by Bayer in Hardeman vs. Monsanto, in which Edwin Hardeman accused the company of failing to disclose the dangers glyphosate poses to human health. Hardeman was awarded $80 million in the case, which was later reduced to $25 million.

"Today's appeals court ruling is another reminder the Biden administration should act and revoke the registration of glyphosate immediately."
—George Kimbrell, Center for Food Safety

Hardeman was diagnosed with non-Hodgkins lymphoma in 2015 after two decades of using Roundup as an herbicide on his 56-acre property. His case was one of several high-profile lawsuits against Monsanto over its use of glyphosate. The company agreed to pay $10.9 billion to a total of about 125,000 people last year, all of whom alleged the use of Roundup was to blame for their cancer diagnoses.

The Environmental Protection Agency backed Bayer in its latest appeal in Hardeman's case, in which the company claimed the jury verdict should be nullified because states don't have the authority to deviate from federal regulations for herbicides.

The three-judge panel ruled that California's failure-to-warn law was consistent with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

"FIFRA did not impliedly preempt Hardeman's state failure-to-warn claims," the court said.

Bayer also claimed that the World Health Organization's classification of glyphosate as a carcinogen should not have been entered into the court record as evidence. The judges ruled that "that the district court did not abuse its discretion in admitting" the evidence.

The Center for Food Safety, which filed an amicus brief in support of Hardeman last year, called the ruling a major victory "for all those who care about protecting human health and the environment and holding corporations accountable for the harm they cause."

Kimbrell said the group was "gratified that the Ninth Circuit unanimously rejected Monsanto's arguments that Mr. Hardeman and thousands of others harmed by their products are prohibited by federal law from suing to redress their injuries. The Court also properly upheld the reliance on the World Health Organization's classification of glyphosate as a probable carcinogen."

Despite international experts' warnings about glyphosate and decisions by policymakers in Austria, Germany, and other countries to phase out or ban the chemical, the EPA still claims that glyphosate is "unlikely to be a human carcinogen."

"Center for Food Safety is currently challenging the federal approval of glyphosate, the active ingredient in Roundup, as unlawful for a number of reasons—including cancer risks to farmers and farmworkers from exposure," said Kimbrell. "Today's appeals court ruling is another reminder the Biden administration should act and revoke the registration of glyphosate immediately."

Judge questions 'actual controversy' in COVID disinfectant suit
N/A, Inside TSCA
https://insideepa.com/tsca-takes/judge-questions-actual-controversy-covid-disinfectant-suit

A federal district judge is questioning whether novel litigation testing EPA's response to COVID-19 remains an "actual controversy," in an order requiring both EPA and the manufacturer that brought the suit to provide updates on their handling of a line of cleaning wipes the agency said were unlawfully marketed as surface disinfectants.

"'[I]n order for a federal court to retain jurisdiction over a case, an actual controversy must exist at all stages of review, not merely at the time the complaint is filed,'" District Judge Lorna Schofield, of the U.S. District Court for the Southern District of New York, writes in a May 12 order to both sides in the case, Tzumi v. EPA.

Tzumi is suing EPA to block a threatened enforcement action over its line of "Wipe-Out!" hand wipes, after the agency claimed in warning letters that the products' label and advertising text amounted to an attempt to sell the wipes as surface cleaners without a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration.

Specifically, EPA objected to text describing the line as "all-purpose disposable wipes" and a product label that says "Use it anytime, anywhere," which the agency said implies that they can be used on surfaces as well as skin. Skin wipes are regulated by the Food and Drug Administration (FDA) rather than EPA.

But Schofield signals in her order that Tzumi appears to have adopted new wording that could resolve EPA's objection, and is directing the firm to file an update with the court by May 19 "providing an estimate of how many, if any, units of the 'Wipe Out!' product bearing the old label are available on store shelves or in Plaintiff's possession."

She notes, "Plaintiff indicated that as of January 2021, nine million units of the 'Wipe Out!' product bearing the label at issue in this case were on store shelves and additional units were in Tzumi's possession," and that "Plaintiff indicated that it has revised the label for the 'Wipe Out!' product and contracted to sell units bearing the revised label."

Schofield is also ordering EPA to "file a status update by May 21, 2021, providing an update on the status of their investigation into the 'Wipe Out!' product."

If Tzumi is no longer selling products with the contested wording, or EPA has wound down its investigation without a formal enforcement action, Schofield could decide there is no longer a live "controversy" and dismiss the case as moot.

That would avoid a substantive ruling in what initially appeared to be a novel test of EPA's aggressive use of FIFRA in response to the COVID-19 pandemic, which Tzumi called a "bureaucratic panic" in earlier filings -- especially after another manufacturer, the California company Zuru, LLC, dropped its suit over the agency's COVID-19 enforcement in March.

Both cases were pushing back against EPA's aggressive use of FIFRA enforcement against companies that it said were improperly selling products as coronavirus disinfectants without FIFRA approval.

Specifically, Tzumi is challenging what it says is the agency's unreasonable reading of its label text, while Zuru said officials overstepped their FIFRA authority by attempting to ban shipments of heavy-duty cleaning wipes registered with the FDA, because they contained an active ingredient used in several EPA-registered surface cleaners.

EPA has argued that the Tzumi case is improper because it has not taken a formal enforcement action against the company, and says that neither its warnings of a potential FIFRA stop sale, use or removal order (SSURO), or a separate advisory letter, are "final action" subject to suit.

"The letter was tentative or interlocutory in nature, rather than a final enforcement action, and it determined no rights or obligations from which legal consequences will flow," EPA argued in a February filing.

Advocates Call for Ban of Toxic Pesticides Linked to Deaths from Chemical Suicides

N/A, Beyond Pesticides Blog
https://beyondpesticides.org/dailynewsblog/2021/05/ban-toxic-pesticides-to-prevent-deaths-from-chemical-suicides/

(Beyond Pesticides, May 13, 2021) Scientists are advocating for stricter pesticide bans to lower deaths from deliberate pesticide ingestion. The request for this toxic pesticide ban follows a University of South Australia study detailing discrepancies in World Health Organization (WHO) classifications of pesticide hazards that rely on animal rather than human data.

Previous studies demonstrate an increased risk of developing depression, especially among agricultural workers and landscapers who use pesticides. Acute exposure to chemicals, including organophosphate and carbamate pesticides, tends to put farmers at greater risk of suicide than the general population. This research highlights the significance of assessing pesticide toxicity and health effects using human data rather than animals to understand health effects resulting from pesticide exposure. Society tends to rank mental health risks second to physical health. However, pesticide poisonings account for one in five suicides globally. Therefore, it is vital to address the accessibility and necessity of conventional pesticide use to safeguard human well-being, especially in countries lacking adequate chemical regulations. The study's scientists note, "The human data for acute toxicity of pesticides should drive hazard classifications and regulation. We believe that a global benchmark for registration of pesticides should include a less than 5% case fatality after self-poisoning, which could prevent many deaths and have a substantial effect on global suicide rate."

Researchers studied a cohort of 34,902 patients (age 11 and up) with possible or known self-poisonings from nine hospitals in rural Sri Lanka. All patients were a part of a South Asian Clinical Toxicology Research Collaboration. Research assistants identified ingested pesticides using historical or physical evidence, as well as blood sample analysis.

From 2002 to 2019, 2,299 (6.6 percent) patients died from pesticide ingestion, with researchers identifying 23,139 specific pesticides among all patients. Although fatalities from pesticide ingestion vary, the highest fatalities occur with paraquat ingestion, 41.8 percent. The most toxic pesticides before 2011 include paraquat, dimethoate, and fenthion, two of which are currently available for use in the U.S. but banned in Sri Lanka. However, post-2013, after Sri Lanka banned the three pesticides, profenofos, propanil, fenobucarb, carbosulfan, and quinalphos, began causing the most deaths—7.2 to 8.6 percent). Deaths from pesticide poisonings are in decline. 2013 to 2019 saw a 3.7 percent death rate compared to 10.5 percent from 2002 to 2006. Although researchers largely attribute the decline in deaths to pesticide bans, there is a modest decline in mortality from non-banned pesticide poisonings.

Individuals suffering from pesticide exposure face a disproportionate risk of developing various health adversaries, including impaired neurological function leading to psychiatric disorders. Exposure to agricultural pesticides puts farmers at six times greater risk of exhibiting depressive symptoms, including chronic anxiety, irritability, restlessness, and sadness. Pesticide exposure from farms or commercially-managed fields threatens residential (non-occupational) populations living nearby who are more likely to have high depressive symptoms. Exposure to organochlorines and fumigants (gaseous pesticides) heighten an individual's risk of depression by 90% and 80%, respectively. Organochlorines are a chemical of concern as it induces a myriad of health problems, including reproductive dysfunction, endocrine disruption, cancer, and fetal defects. Though the U.S. bans the use of many organochlorines, these chemicals can still expose individuals to volatile concentrations as they are highly persistent in the environment. Fumigants are a human health concern as many fumigants are gases that can cause acute toxicity upon inhalation and ingestion. Linear models reveal...

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